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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/664,871 09/19/00 MACH

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EXAMINER

STILLER, K

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

06/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/664,871

Applicant(s)

MACH, FRANCOIS

Examiner

Karl Stiller

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claims 1-39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-32, and 35-39, drawn to a method to achieve MHC-Class II mediated immunomodulation or anti-inflammatory effect, or regulating IFN- γ induced CIITA expression and CIITA-dependant inter- or intra-cellular events, or a method of treating, preparing, or preventing tissue or organ rejection in a mammal comprising administering at least one statin, or a functionally or structurally equivalent molecule, diversely classified in Class 514, for example, Subclasses 183, 277, 333, 406, 415, 427, 460, 510, etc.
- II. Claims 33-34, drawn to a method for identifying molecules that inhibit IFN- γ induced CIITA expression, classified in Class 435, Subclass 41.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I-II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The invention of Group I is a method which functions to achieve MHC-Class II mediated immunomodulation or anti-inflammatory effect, or regulate IFN- γ induced CIITA expression and CIITA-dependant inter- or intra-cellular events, or to treat, prepare, or

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prevent tissue or organ rejection in a mammal comprising administering at least one statin, or a functionally or structurally equivalent molecule. The invention of Group II is a method which functions to identify molecules that inhibit IFN- γ induced CIITA expression. Therefore, the function of Groups I-II differ.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Election of Species

If applicant elects Groups I, applicant is further required to elect a single disclosed specified statin or a combination of individual statins useful in the methods herein and individual diseases or conditions to be treated, e.g. type I diabetes, multiple sclerosis, psoriasis, kidney transplant, etc. (see claims 7-12) as a specie under 35 U.S.C. 121 to which the claims shall be restricted if no generic claim is finally held to be allowable, even though this requirement is traversed. Claims 1-32, and 35-39 are generic to a plurality of disclosed patentably distinct species comprising individual statins or a combination of individual statins useful in the methods herein and individual diseases or conditions to be treated.

The search for all species of individual agents useful in the methods herein presents an undue burden on the office due to their structural dissimilarities. Note, for example, that fluvastatin is classified in Class 514, Subclass 415, simvastatin is

classified in Class 514, Subclass 460, atorvastatin is classified in Class 514, 427, pravastatin sodium is classified in Class 514, Subclass 510, and cerivastatin is classified in Class 514, Subclass 277. The chemically related or structurally equivalent agents including individual HMG-Co A reductase inhibitors and/or inhibitors of MHC Class II expression are also diversely classified. For example, (3R, 5S, 6E, 8E)-9, 9-bis- (4-fluorophenyl)-3,5-dihydroxy-8- (1-methyl-1*H*-tetraazol-5-yl) deca-6, 8-dienoate is classified in Class 514, Subclass 183, (3R, 5S, 6E)-7-[5-(4-fluorophenyl)-3-isopropyl-1-1pyridin-3-yl-1*H*-pyrazol-4-yl]-3,5-dihydroxy hept-6-enoic acid is classified in Class 514, Subclass 333, and (3R, 5S, 6E)-7-[5-(4-fluorophenyl)-3-isopropyl-1-pyrazin-2-yl-1*H*-pyrazol-4-yl]-3,5-dihydroxy hept-6-enoic acid is classified in Class 514, Subclass 406.

Therefore, due to the structural diversity of active compounds useful herein and their corresponding diverse classification, the search for all species of statin or combinations of individual statins would present an undue burden on the office.

The search for all species of diseases or conditions requiring MHC-Class II mediated immunomodulation or anti-inflammatory effect, or regulation of IFN- γ induced CIITA expression and CIITA-dependant inter- or intra-cellular events presents an undue burden on the office due to their separate and distinct fields of search. Note that the search is not limited to the patent files. The claims are drawn to the treatment of many autoimmune diseases, inflammatory conditions, and conditions requiring immunomodulation, for example, rheumatoid arthritis, psoriasis, and kidney transplant. The search fields for rheumatoid arthritis, psoriasis, and kidney transplant differ.

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Rheumatoid arthritis is routinely treated with non-steroidal anti-inflammatory drugs, methotrexate, and infliximab, whereas psoriasis and kidney transplant patients are not. Psoriasis is routinely treated with calcipotriene in combination with a topical corticosteroid, whereas rheumatoid arthritis and kidney transplant patients are not. Kidney transplant patients are routinely treated with antibiotics, mycophenolate mofetil, and tacrolimus, whereas rheumatoid arthritis and psoriasis are not.

Therefore, due to the characteristic diversity of medical disorders within the claims and their treatment in the art, the search for all species of individual disorders would present an undue burden on the office.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was made to Michael H. Teschner on May 29, 2001 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karl Stiller whose telephone number is 703-306-3219. The examiner can normally be reached Monday through Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached at 703-308-4612. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4556 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Stiller: ks
May 29, 2001


MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1800